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In the Supreme Court of the United States

OCTOBER TERM, 1944

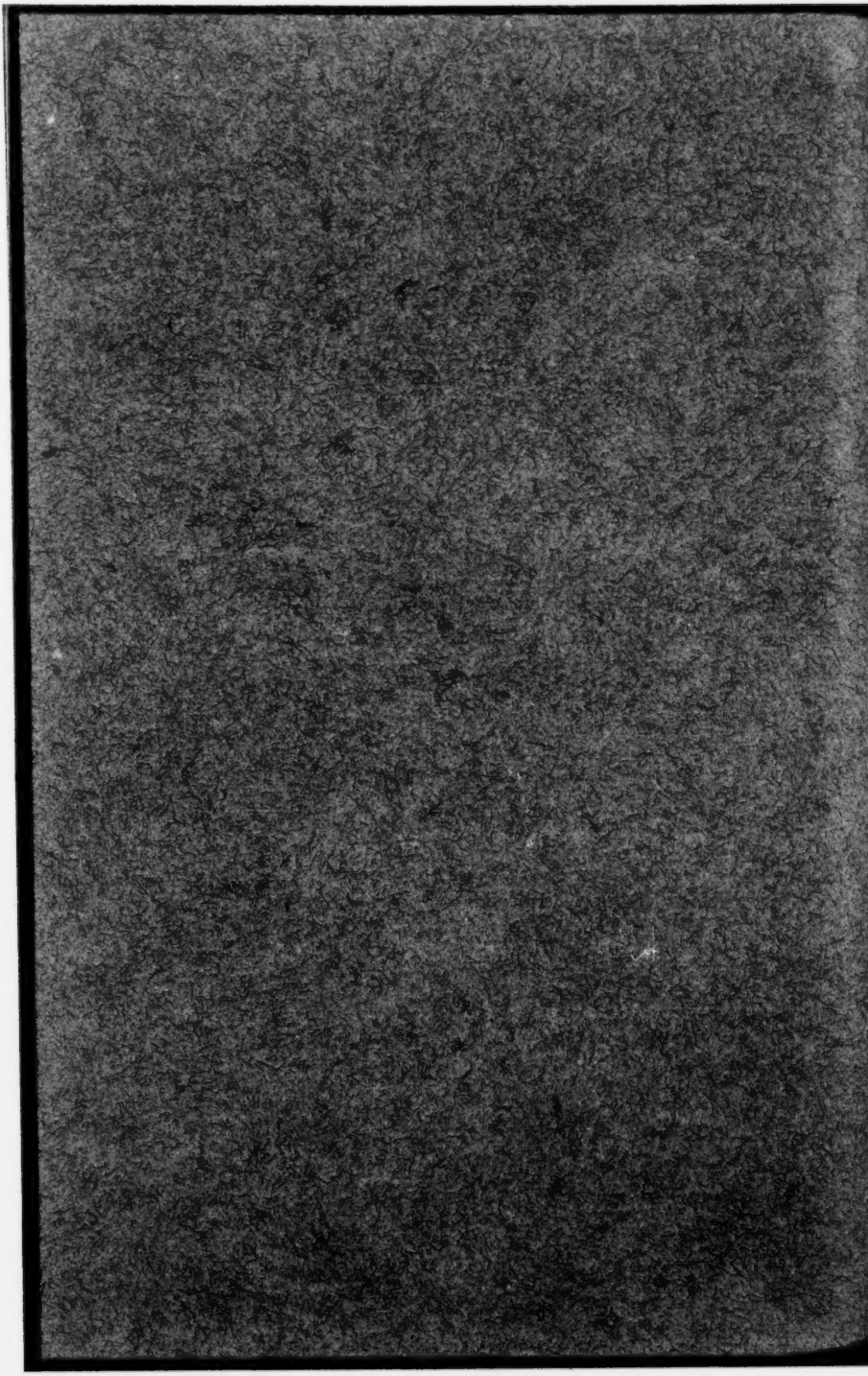
RALADAM COMPANY, AS CLAIMANT OF 62 PACKAGES, MORE OR LESS, OF MARMOLA PRESCRIPTION TABLETS, PETITIONER

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES CIRCUIT COURT OF APPEALS FOR THE SEVENTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION



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OPINIONS BELOW

The opinion of the circuit court of appeals (R. 1353–1359) is reported at 142 F. (2d) 107. The memorandum opinion of the district court (R. 1298–1315) is reported at 48 F. Supp. 878.

JURISDICTION

The judgment of the circuit court of appeals was entered May 4, 1944 (R. 1360). The petition for a writ of certiorari was filed August 3, 1944. The jurisdiction of this Court is invoked under

Section 240 (a) of the Judicial Code, as amended by the Act of February 13, 1925.

QUESTIONS PRESENTED

The principal questions presented are:

1. Whether a drug is misbranded within the meaning of Section 502 (j) of the Federal Food, Drug, and Cosmetic Act, if, when used in accordance with the directions contained in its labeling, it endangers public health, even though the labeling contains no false or misleading statement.

2. If so, whether the Act is unconstitutional as an interference with the practice of self-medication and as lacking an ascertainable standard for determining when a drug is misbranded.

3. Whether the evidence is sufficient to sustain the findings of the trial judge, concurred in by the circuit court of appeals, that petitioner's product was dangerous to health when used in the dosage, and for the duration of time, prescribed in its labeling, and, therefore, was misbranded under Section 502 (j) of the Federal Food, Drug, and Cosmetic Act.

STATUTE INVOLVED

The Federal Food, Drug, and Cosmetic Act (Act of June 25, 1938, c. 675, 52 Stat. 1040, 21 U. S. C. 301 et seq.), provide in part:

* * * * *

> SEC. 304. (a) Any article of food, drug, device, or cometic that is adulterated or misbranded when introduced into or while

in interstate commerce, * * * shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found: * * *.

* * * * *

SEC. 502. A drug or device shall be deemed to be misbranded

* * * * *

(j) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

STATEMENT

Proceeding under Section 304 of the Federal Food, Drug, and Cosmetic Act, the United States, on April 11, 1939 (R. 1), filed a libel of information in the District Court of the United States for the Western District of Wisconsin, which was amended on January 8, 1940 (R. 5), against approximately 62 packages of a drug product called Marmola on the ground that it was misbranded under Section 502 (j) of the Act[1] in that it was

[1] The Government also proceeded under Section 502 (a) and 201 (n) of the Act (21 U. S. C. 352 (a) and 321 (n)) and the trial court based the decree of condemnation on these sections as well as on Section 502 (j) (R. 13–26). The circuit court of appeals, however, relied solely upon Section 502 (j) in affirming the decree and petitioner's contentions are directed only to that provision. We, therefore, confine our discussion to Section 502 (j), without, however, waiving reliance on Sections 201 (n) and 502 (a).

dangerous to health when used as prescribed in its labeling (R. 5–7). Petitioner intervened as claimant (R. 3, 5) and the case was tried before the court without a jury.

The Government's libel of information was based on the contention that the seized Marmola Prescription Tablets were dangerous to health because each contained one-half grain of desiccated thyroid (R. 13) [2] and the labeling of the product directed that four tablets be taken each day over a period of 60 to 90 days (R. 9). In support of its claim that the taking of four Marmola tablets each day was dangerous to health, the Government's proof showed that the consumption of two grains of desiccated thyroid of the United States Pharmacopoeia standard constitutes an overdose for many persons. The proof in this respect may be summarized as follows:

When the thyroid gland fails to produce a sufficient amount of thryoxin, which is, or is contained in, the hormone of the thyroid gland, a condition known as hypothyroidism appears. This condition is made evident by such symptoms as thickened and coarsened skin, falling hair, sluggishness of mind and body, a puffy appearance due to a mucoid deposit under the skin, and changes in the

[2] It was stipulated at the trial that "the only ingredient of Marmola Prescription Tablets that is involved in this action is the ½ grain of Desiccated Thyroid contained in each tablet" (R. 19).

blood chemistry, and is accompanied by a depression in the basal metabolic rate. (R. 39, 582–584, 672–674, 690, 700–701, 781, 919.)

If the thyroid gland produces too much of its hormone, a condition known as hyperthyroidism results. This disease is manifested by many signs and symptoms, such as headaches, nausea, vomiting, tachycardia, heart pains, palpitation of the heart, sweating, nervousness, and sleeplessness. In its severe stages, it is usually accompanied by loss of weight. (R. 40, 584, 681, 692, 782–790.) Hyperthyroidism does not cause organic or pathological changes but does induce misfunctions which may be so severe as to cause death (R. 930, 938, 939).

Desiccated thyroid is obtained from the thyroid glands of food animals. When it is administered to a human being it has the same effect as thyroxin spontaneously produced; that is, if a person is deficient in thyroxin the symptoms of hypothyroidism will disappear as the dosage of desiccated thyroid reaches the point where it replaces the deficiency of the thyroxin. If, however, the dosage furnishes more thyroxin than is necessary to maintain the normal functioning of the body, the signs and symptoms of a spontaneous hyperthyroidism appear. (R. 47–48, 421, 587–588, 677–681, 789–790, 806–807, 1163, 1188.)

Persons differ in their tolerance for the drug, and the limit of tolerance can be determined only

by trial and error (R. 90, 247–250, 588–590, 591, 607–608, 637–638, 923–926). All persons who obtain an overdose of desiccated thyroid develop the well-recognized symptoms of hyperthyroidism. Two grains of desiccated thyroid of United States Pharmacopoeia standard [3] constitute overdosage for many persons, that is, on such a daily dosage a considerable proportion, even those who are hypothyroid, will develop symptoms of hyperthyroidism (R. 248, 402–404, 422, 444–446, 470–473, 562–565, 591, 638, 644, 652–653, 662–663, 790–792). These symptoms are not the reactions of allergies or idiosyncrasies (R. 201–213, 496–497).

Moreover, many persons, without realizing it, are suffering from or are extremely susceptible to an illness; that is, such pathological changes may be occurring in their organs, or the reserves of some organs may be so depleted, that these persons cannot withstand extra strain (R. 49–51, 177–180, 484–485). In these persons, the inducing of symptoms of hyperthyroidism accelerates the onset of, or precipitates, the more serious stages of diseases which they may have or to which they may be susceptible or prevents curative measures from being effective (R. 389, 736–738). This is especially true of diabetes (R. 485–495, 497–498) and

[3] The desiccated thyroid used in petitioner's product possesses one and one-half times the potency of that made in accordance with the standard of the United States Pharmacopoeia (R. 18–19; see also R. 1357).

heart disease (R. 559–568, 642–643, 677–679, 692–693). The induced symptoms of hyperthyroidism also contribute to the precipitation of certain functional diseases, such as amenhorrhea, Graves' Disease, and psychoneuroses (R. 788–789, 793–798, 803–804).

On this evidence the trial court found, among other things, that the desiccated thyroid contained in petitioner's tablets produces greater physiological effects than the same quantity prepared according to the standard of the United States Pharmacopoeia (Finding 4, R. 1316), and that (R. 1326):

> 21. The use of two grains of desiccated thyroid daily without medical supervision is dangerous to users.
>
> 22. The Marmola Prescription Tablets, when used as a treatment for obesity in daily dosages of four tablets for the duration of time suggested in the labeling, are dangerous to the health of users.

The trial court concluded as a matter of law (Conclusion 3, R. 1326) that the tablets were misbranded as alleged in the libel of information, and entered a decree of condemnation (R. 1327–1328). On appeal to the Circuit Court of Appeals for the Seventh Circuit the decree was affirmed (R. 1360).

ARGUMENT

1. Contrary to the basic premise of petitioner's entire argument (Pet. 14–17, 24–49), neither the

trial court nor the circuit court of appeals held that Section 502 (j) of the Act is designed to put an end to "the labeling of effective dosages of useful drugs * * * for self-medication" (e. g., Pet. 32) merely because of potential dangers which may be inherent in the drug as such. Rather, the courts held in plain and unambiguous language confined to a single product, petitioner's, that it is misbranded because when used in the manner prescribed, suggested, and recommended in its labeling, it endangers the public health, even though the labeling contains no false or misleading statement and contains the information required by the other sections of the Act.

McDermott v. *Wisconsin*, 228 U. S. 115, 133, upon which petitioner relies (Pet. 14–15, 20–21, 24, 57–59), was not concerned with a provision such as Section 502 (j), and therefore does not aid petitioner in any respect. In that case this Court held invalid a State law the effect of which was to cause the removal of a label that, in accordance with the provisions of the Food and Drugs Act of 1906 (21 U. S. C., 1934 ed., 1 et seq.), had been properly placed on a food shipped in interstate commerce. The reason given by this Court was that "the label is the means of vindication or the basis of punishment in determining the character of the interstate shipment dealt with by Congress." Likewise, in the present case the label must be relied on to ascertain whether the

prescribed use of the product renders it dangerous to the public health.[4]

The construction placed on Section 502 (j) by the courts below accords fully with the design of Congress. The legislative history discloses that, in enacting the section, it was intended to amplify and extend the provisions of the Food and Drugs Act of 1906 so as to close the channels of interstate commerce to a drug product which is dangerous when used according to its labeling even though it does not contain false or misleading statements. This is set forth clearly in Senate Report No. 646, 74th Cong., 1st sess., pp. 7–8, accompanying S. 5, a precursor to the bill which was enacted into law. The report stated:

> Paragraph (b) defines a drug or device as misbranded if it is dangerous to health under the conditions of use prescribed in its labeling or advertising. There are no useful products which would be barred from the market under this provision, since labeling with proper directions for use would remove any worth-while article from this ban. Under the present law, which

[4] Petitioner erroneously conceives Section 502 to be a mislabeling section in the ordinary sense of that term; that is, the label itself must *per se* be false or misleading (see *e. g.*, Pet. 24, 26–28, 37). However, it is evident from those definitions of misbranding contained in the paragraphs of the section following paragraph (a) that a product may be misbranded even though its label is not false or misleading (see Section 502 of the Act as copied at pp. 12–13 of the Appendix to the petition for a writ of certiorari).

contains no provision of this character, there have come on the market a number of dangerous drugs from the use of which many authenticated cases of death and impairment of health have been reported. So long as their labels bore no false or misleading statements, the public could not be protected.

There are certain drugs whose employment is necessary in the treatment of some diseases, which none the less may in very exceptional cases prove harmful to persons to whom they are administered. Their action in such circumstances is comparable to the allergic action of eggs and other common foods, which was discussed in connection with paragraph (a) of section 301. It is not intended that this provision should ban the sale of useful drugs of this kind when they are appropriately labeled. On the other hand, it is not intended that the existence of these drugs shall constitute a cloak under which may hide the manufacturers of unnecessary and dangerous medicaments; or even necessary medicaments with improper or insufficient directions for use that result in the injury of susceptible persons in any considerable number of instances even though most persons could use them with safety. Much criticism has been launched at this provision on the ground that it applies to innocuous drugs for which extravagant therapeutic claims are made and which thus indirectly impair the patient's chance of recovery through his post-

> ponement of proper methods of treatment. The language does not relate to such products. It applies only to potent drugs which are per se harmful unless properly administered.

Petitioner's contention (Pet. 32–39) that the circuit court of appeals construed Section 502 (j) in a manner inconsistent with the other subsections of Section 502 is without merit, for it is based on petitioner's basic misapprehension that the court predicated its decision on the assumption that the subsection prevents the labeling and consumption of desiccated thyroid. It is clear, however, that the court did not so hold. What it did decide was that the drug, under the terms of Section 502 (j), was misbranded because its labeling prescribed a dosage which made the product dangerous to the public health, notwithstanding that it may have complied with the other subsections; and that a drug, to escape being misbranded, must comply with every provision of Section 502. This leads to no inconsistency between the various provisions of the section, which supplement rather than conflict with each other. To offend against any one of the subsections constitutes a misbranding, whether it relates to informative labeling, the form or fill of the container, or dangerous dosage. See *Weeks* v. *United States*, 245 U. S. 618, 621.

2. Petitioner's further contention (Pet. 50–58) that, as construed by the circuit court of appeals, Section 502 (j) is unconstitutional as an unwar-

ranted interference with the practice of self-medication and because it contains no ascertainable standard for determining when a drug is misbranded, is without merit.

As we have pointed out, the decisions below did not deal with the practice of self-medication as such. They related only to a product which, on the basis of the evidence before the courts, was found to be dangerous to the public health when taken in the manner recommended by the manufacturer. There can be no doubt of Congress' power to prohibit the transportation of such an article in interstate commerce.

The power of Congress to regulate commerce "is complete in itself, may be exercised to its utmost extent, and acknowledges no limitations, other than are prescribed in the constitution." *Gibbons* v. *Ogden,* 22 U. S. 1, 196; *United States* v. *Darby,* 312 U. S. 100, 113, 114. The power may be exercised to keep interstate commerce "free from the transportation of illicit or harmful articles, to make such as are injurious to the public health outlaws of such commerce and to bar them from the facilities and privileges thereof." *McDermott* v. *Wisconsin,* 228 U. S. 115, 128. This Court has upheld the right of Congress to close the channels of interstate commerce to a product found to be adulterated notwithstanding the honesty of its label. *United States* v. *Carolene Products Co.,* 304 U. S. 144, 151. And under both the Food and Drugs Act of 1906

and the Federal Food, Drug, and Cosmetic Act, it has been held that the design of the statutes was not confined to a requirement of truthful and informative labeling. *United States* v. *Coca Cola Co.,* 241 U. S. 265, 277, 278; *Federal Security Administrator* v. *Quaker Oats Company,* 318 U. S. 218, 230.

Nor is there wanting a reasonable standard whereby the question of misbranding under the section may be determined Whether a prescribed use of a drug is dangerous to the public health is as susceptible of proof as is the question whether a product contains any added or deleterious substances which may render it injurious to health; and compliance or noncompliance with either standard is equally susceptible of determination. In respect of the latter standard as contained in Section 7 of the Food and Drugs Act of 1906 (21 U. S. C., 1934 ed., 8), this Court found no such difficulty as petitioner perceives. *United States* v. *Coca Cola Co.,* 241 U. S. 265; *United States* v. *Lexington Mill and Elevator Company,* 232 U. S. 399.

3. There is no warrant for petitioner's contention (Pet. 59–60) that the evidence is insufficient to support the findings of the trial judge. The evidence, summarized in the Statement, *supra,* pp. 4–7, shows that two grains per day of desiccated thyroid of United States Pharmacopoeia standard constitute an overdosage for many persons, even those who are hypothyroid; that the daily dosage

of desiccated thyroid prescribed in the labeling of petitioner's product was two grains; and that the desiccated thyroid contained in petitioner's product produces greater physiological effects than a similar amount prepared pursuant to the United States Pharmacopoeia standard. No witness questioned the facts shown by the Government's evidence that an overdosage of desiccated thyroid produces the symptoms of hyperthyroidism and that when such symptoms appear diabetes, tuberculosis, and certain heart diseases are aggravated; that an overdosage sometimes causes amenorrhea; and that excessive thyroid medication heightens and exaggerates existing excited and unstable mental, nervous, and emotional states, which are precipitating factors of Graves' Disease and psychoneuroses. As the court below stated (R. 1358), "We think the evidence such as to justify only the conclusion reached by the trial court. We certainly are not justified in saying that the finding is erroneous as a matter of law. Admittedly, taking four tablets a day, is not dangerous to the health of all users, since tolerance for the drug varies; but the experience of various witnesses, all of whom took tablets according to the directions on the label, as well as the testimony of a number of medical experts, inevitably impel one to the finding that use of the tablets as prescribed is dangerous to the health of the public. * * *"

CONCLUSION

The decision of the circuit court of appeals is correct, the case presents no question of general importance, and there is involved no conflict of decisions. We respectfully submit, therefore, that the petition for a writ of certiorari should be denied.

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